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Park et al.

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(54) **PRECISION ROLLER CLAMP**

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A61M 5/168 (2006.01)
A61M 5/14 (2006.01)

(52) **U.S. Cl.**
CPC ***A61M 39/286*** (2013.01); ***A61M 5/1411*** (2013.01); ***A61M 5/16813*** (2013.01); ***A61M 5/16881*** (2013.01); ***A61M 39/281*** (2013.01); *A61M 2205/33* (2013.01)

(58) **Field of Classification Search**
CPC A61M 2205/3337; A61M 39/286; A61M 39/287; A61M 5/16813; A61M 5/16881; A61M 39/285
See application file for complete search history.

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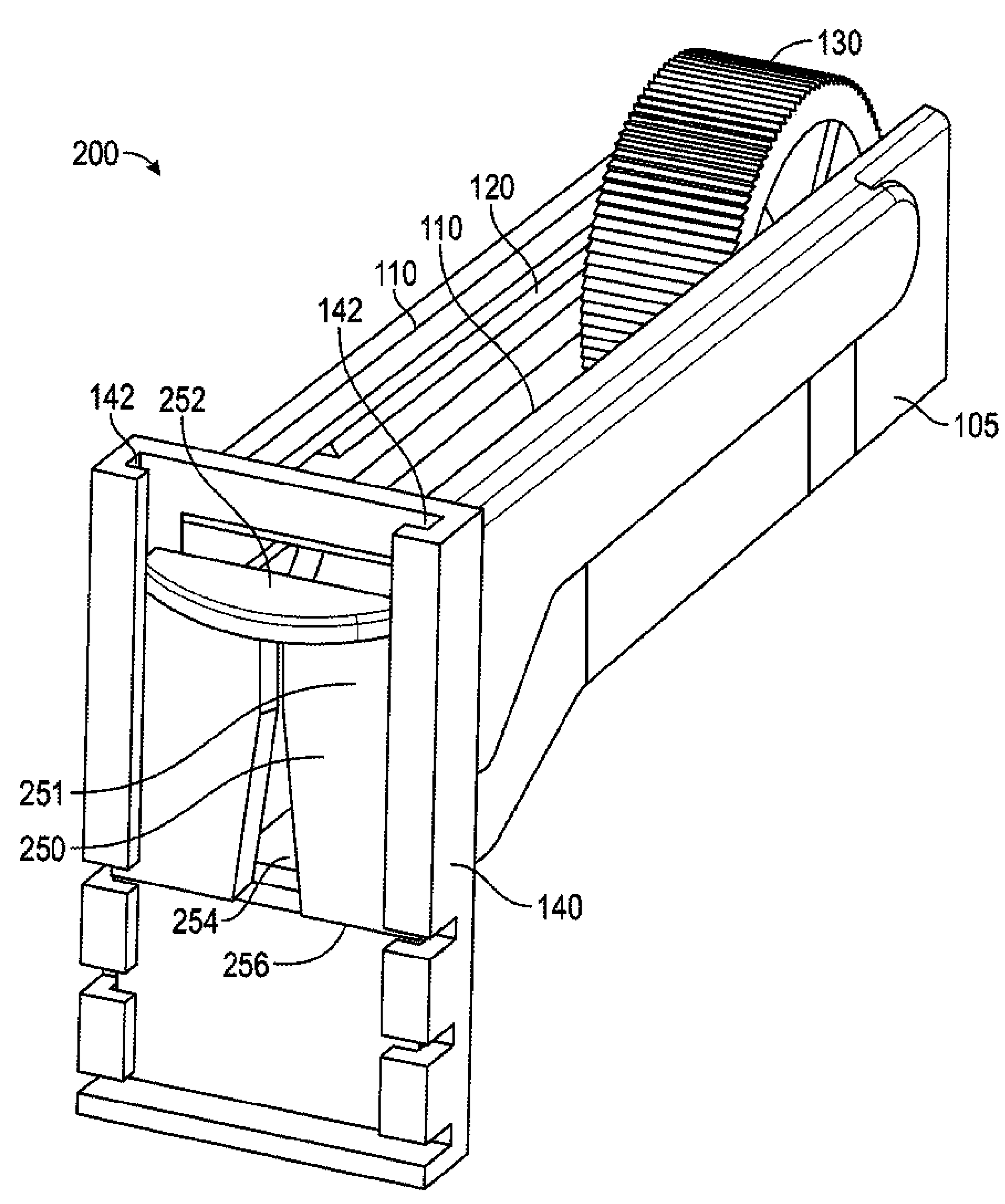
(57) **ABSTRACT**

A roller clamp assembly for adjusting the fluid flow rate in a connector tube of an infusion set is provided. The roller clamp assembly includes a housing to receive the connector tube, a plate slideably engaged with the housing and configured to rapidly compress the connector tube to provide a coarse fluid flow adjustment, and a roller wheel moveable engaged with the housing and configured to provide a gradual fluid flow adjustment. The plate may be a slide plate received by grooves in an exterior wall of the housing and that moves orthogonally to the connector tube, or the plate may be a shim plate that moves along an interior wall of the housing in parallel to the connector tube. Infusion sets and methods of adjusting fluid flow rates are also provided.

18 Claims, 14 Drawing Sheets



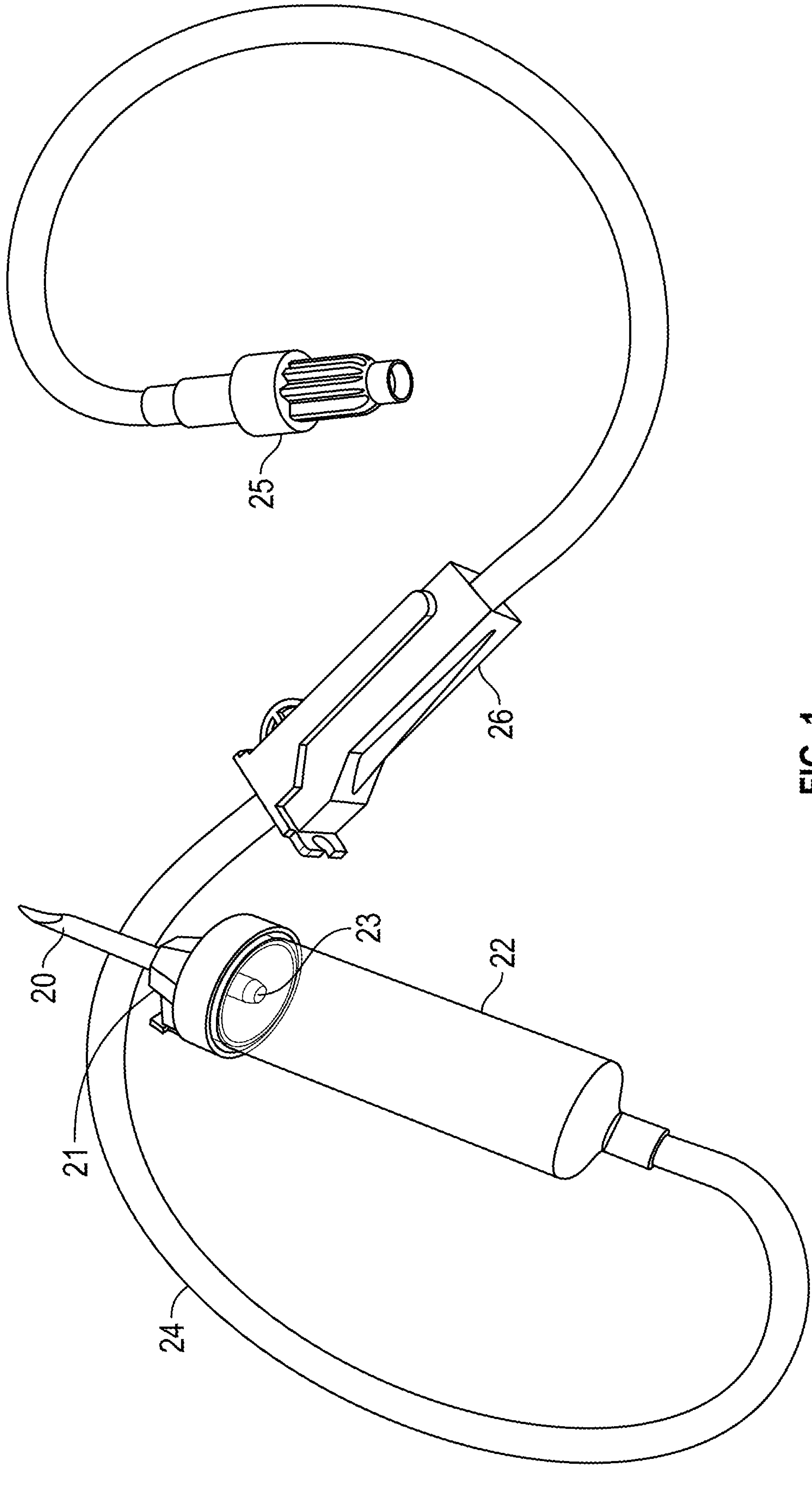


FIG. 1
(Prior Art)

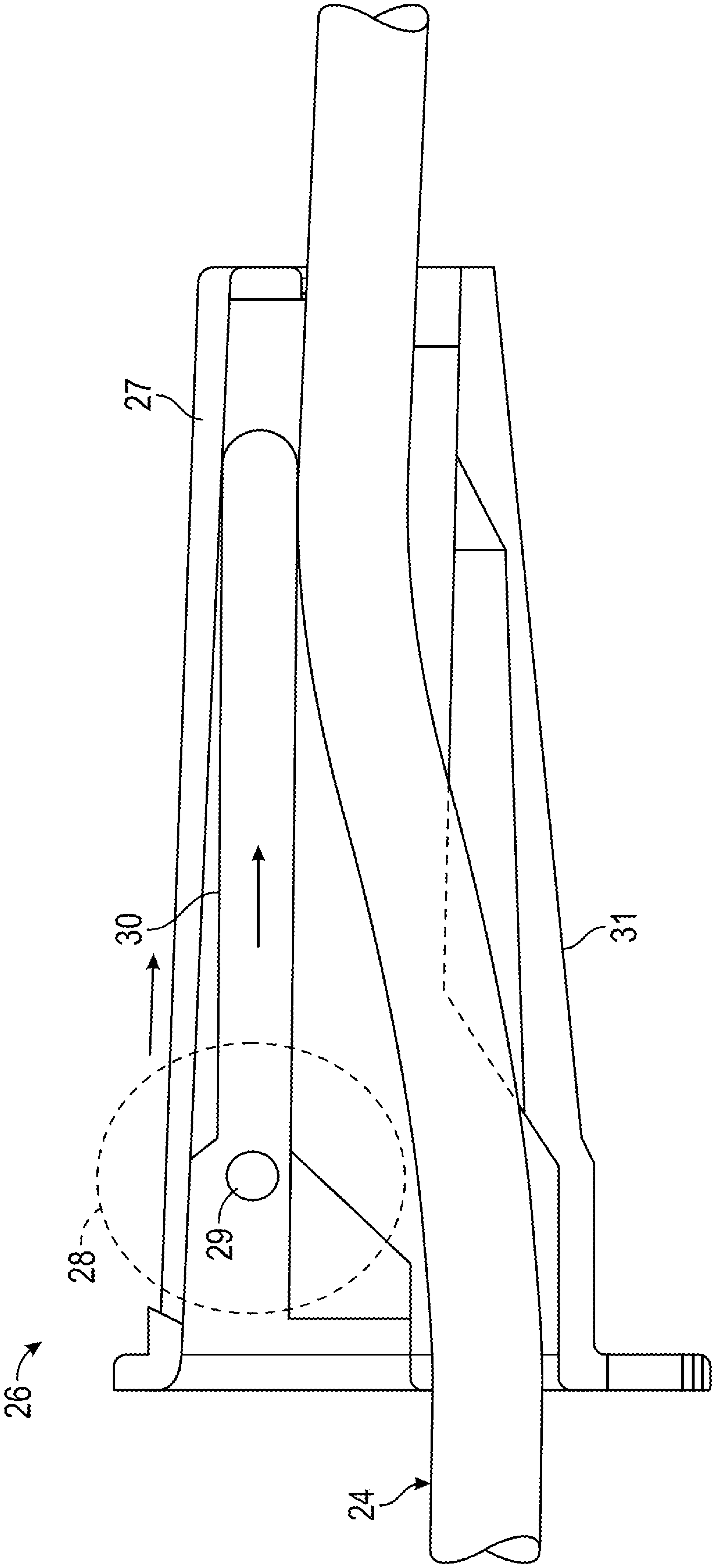


FIG. 2
(Prior Art)

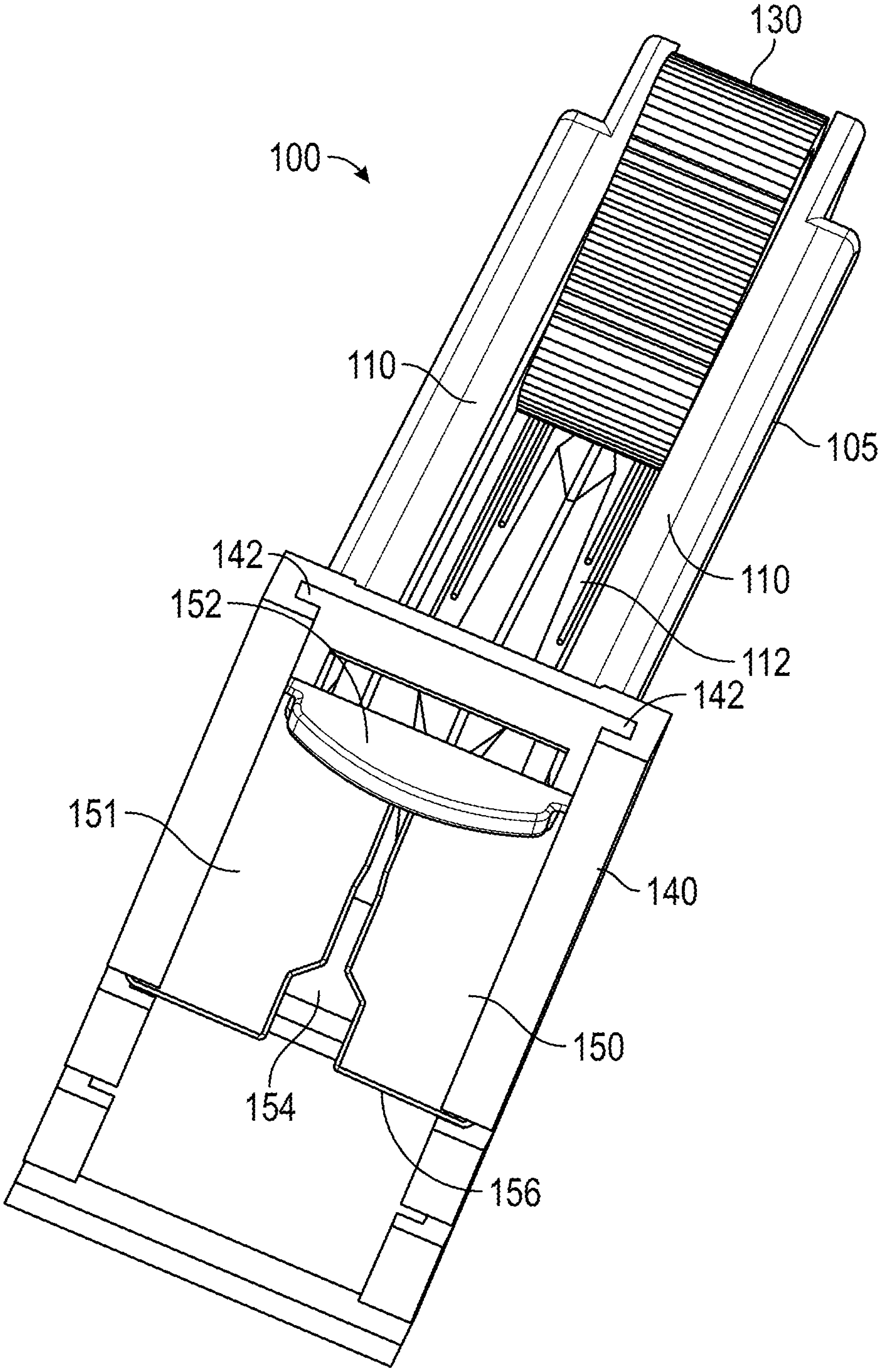


FIG. 3

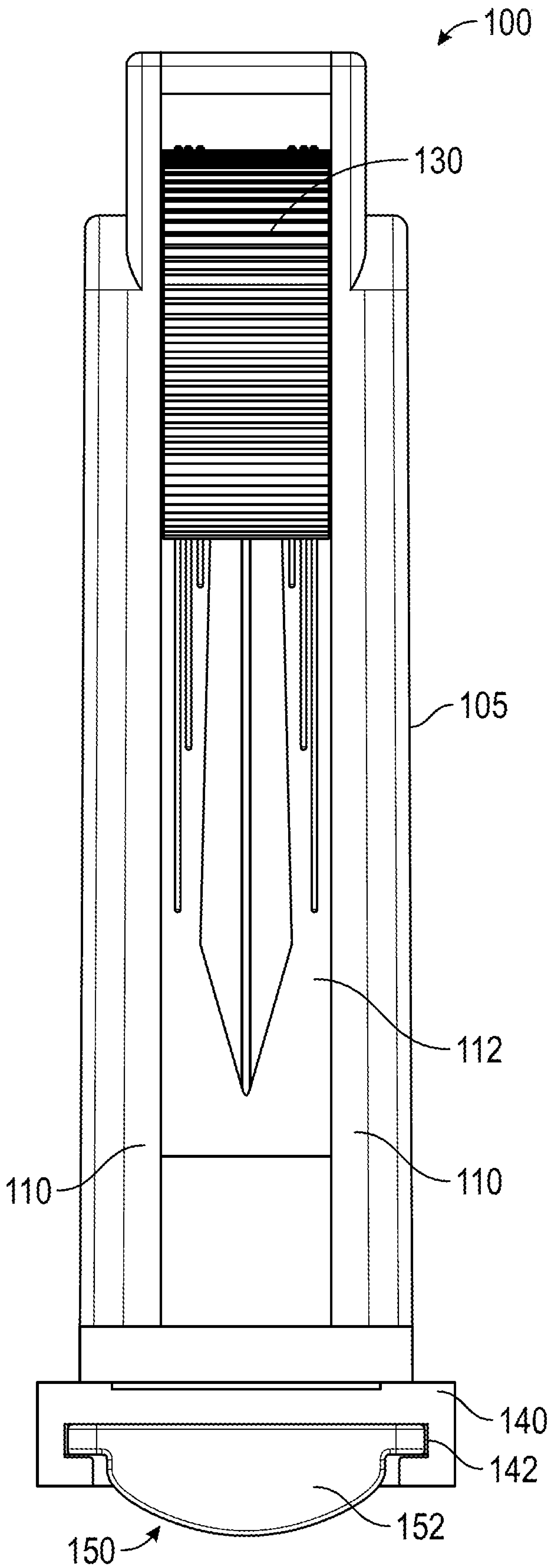


FIG. 4

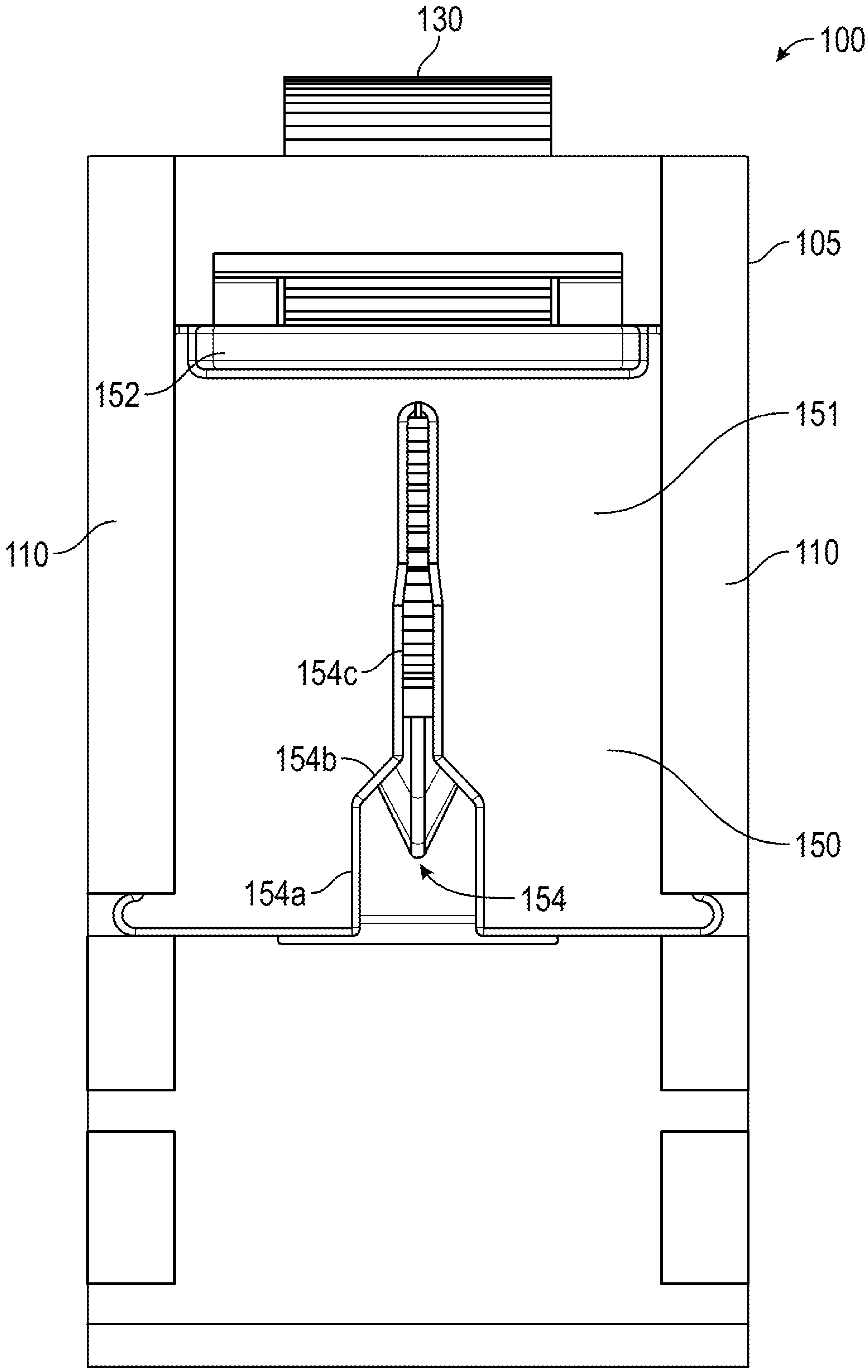


FIG. 5

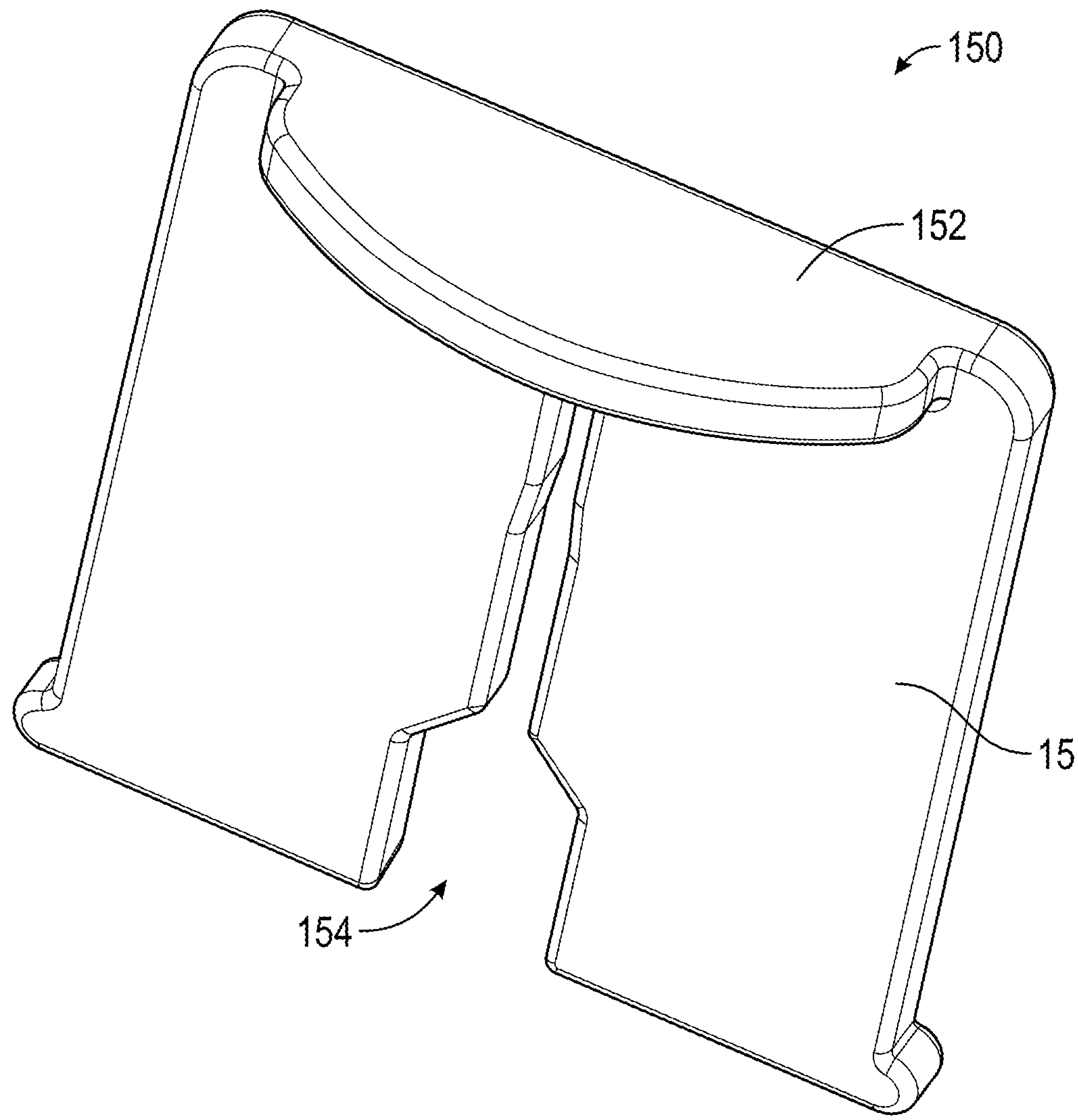


FIG. 6

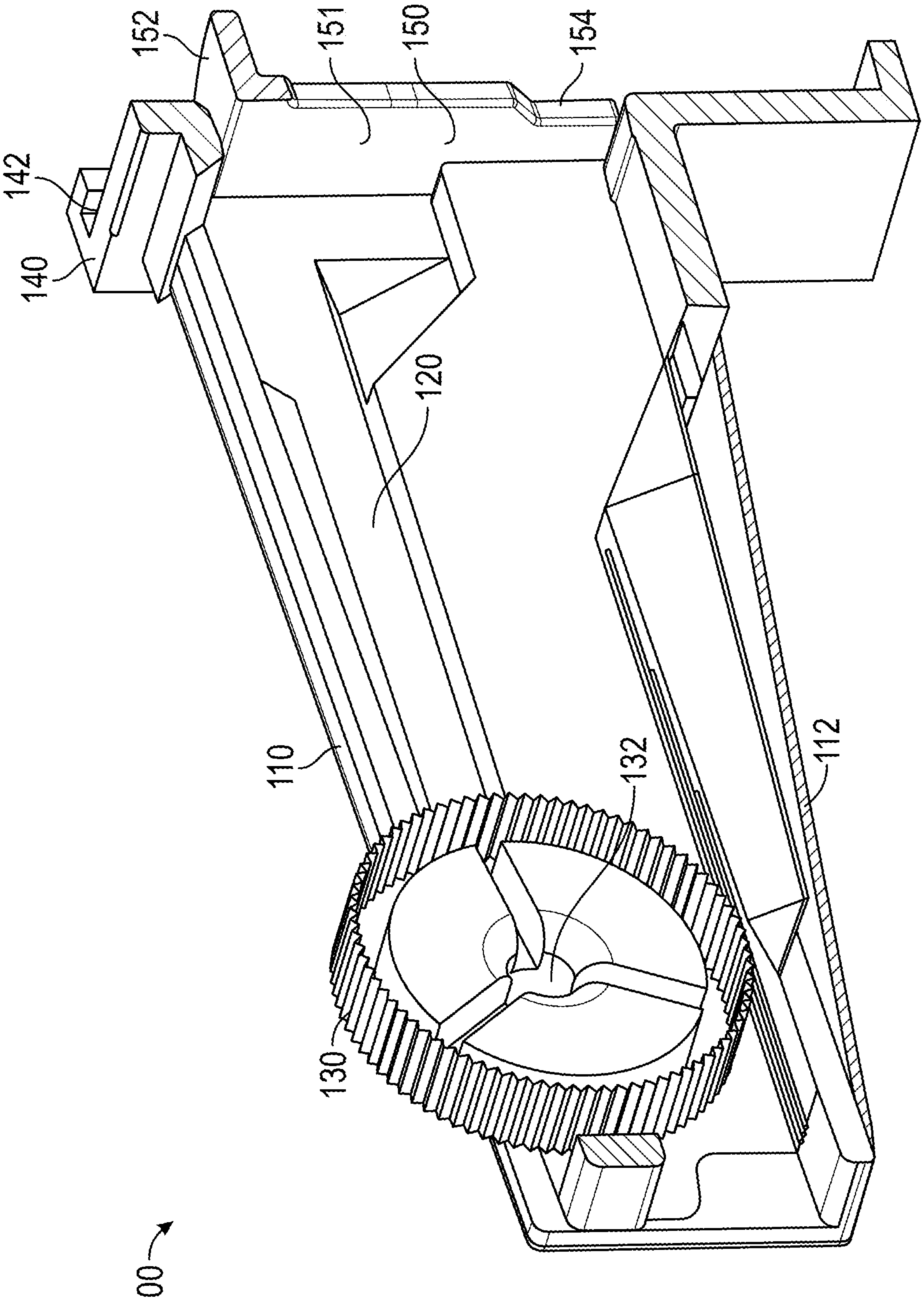


FIG. 7

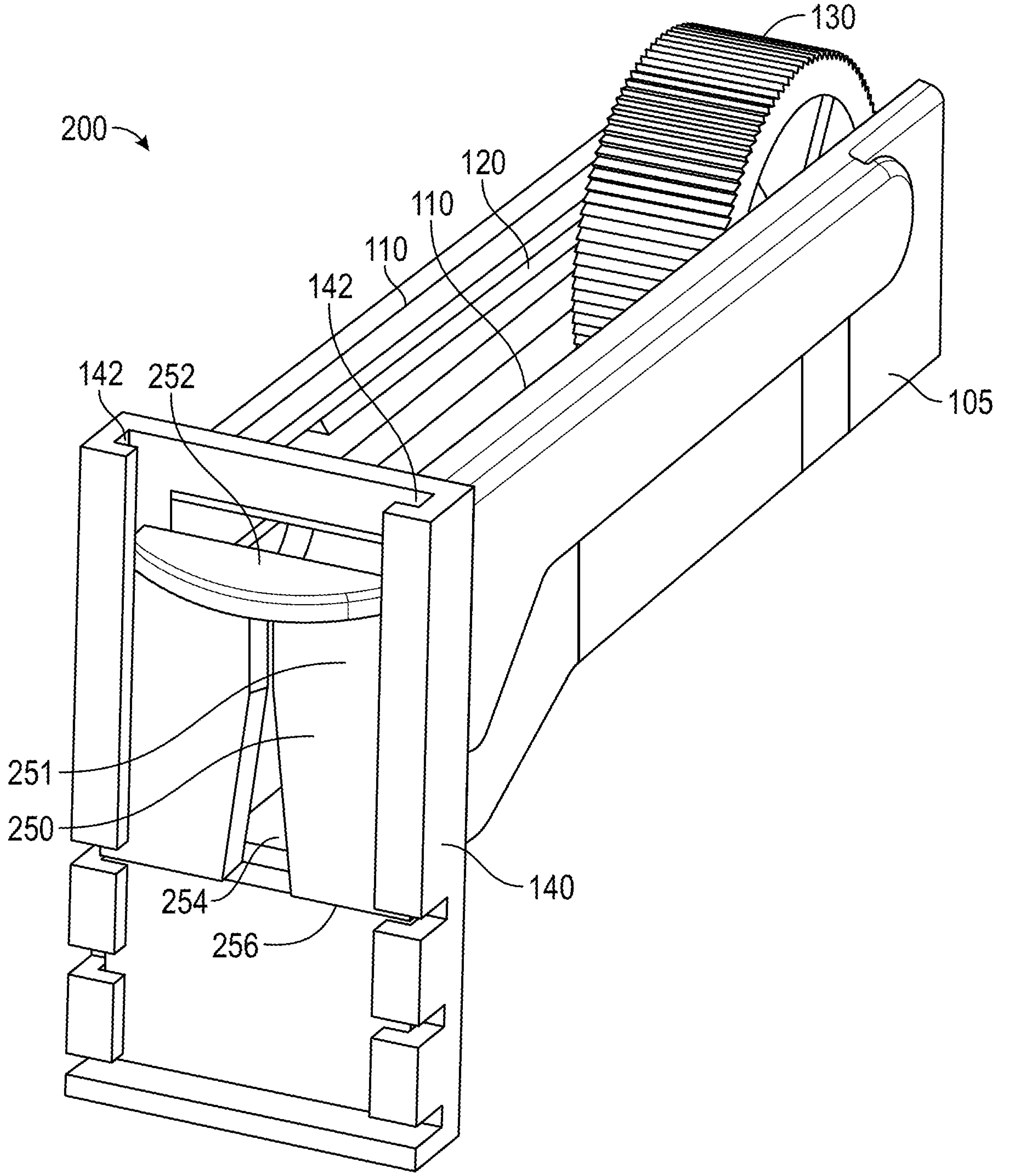


FIG. 8

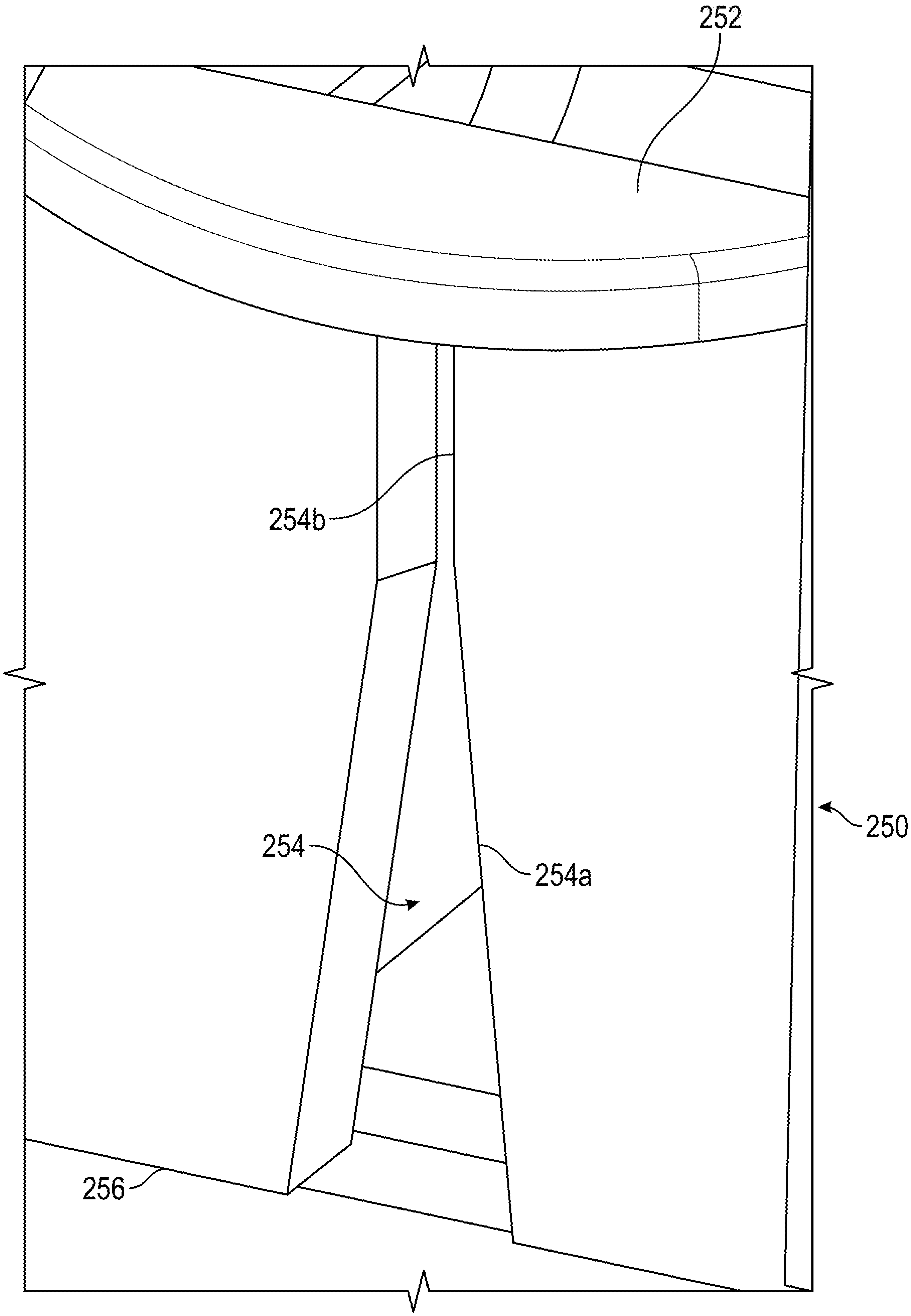


FIG. 9

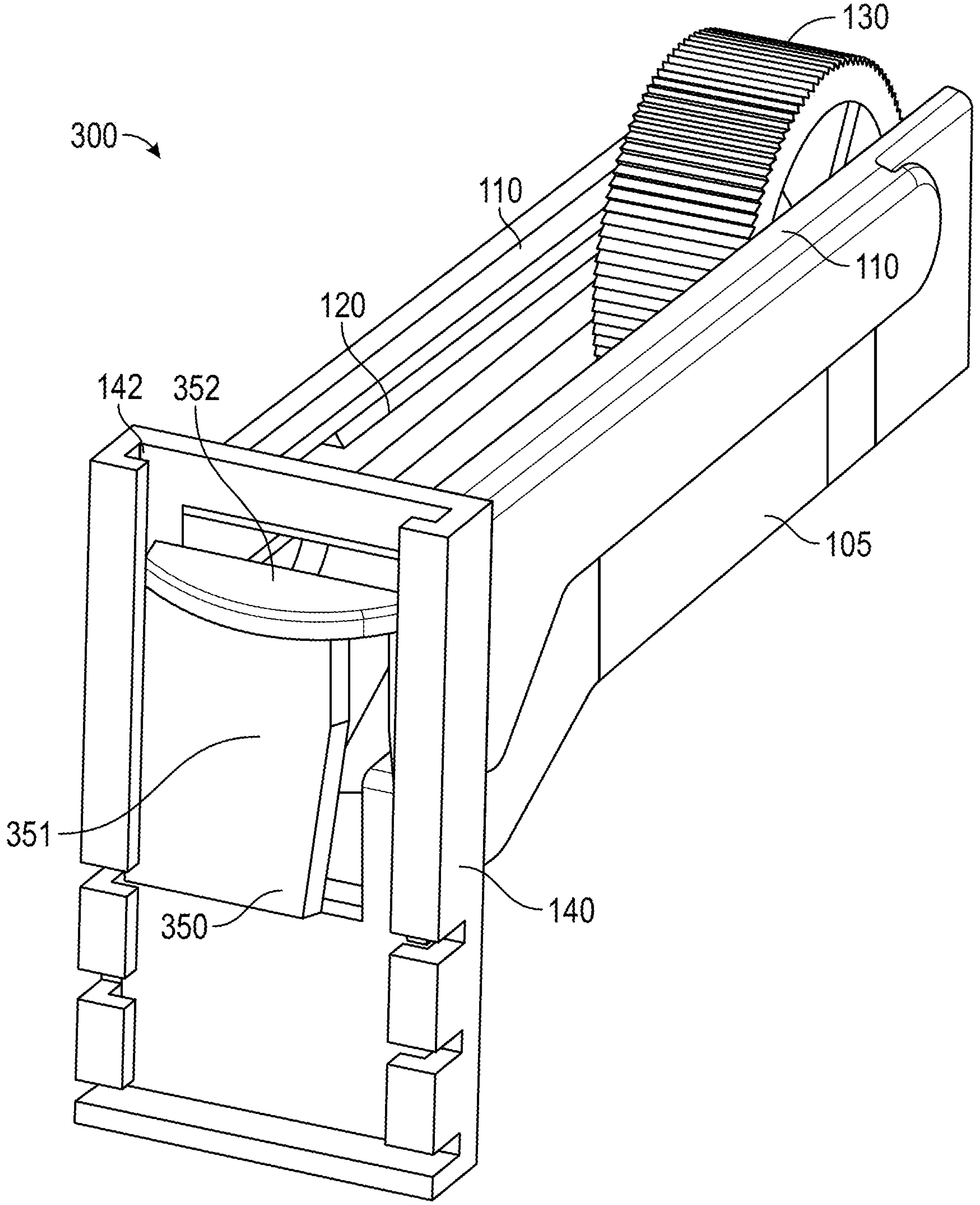


FIG. 10

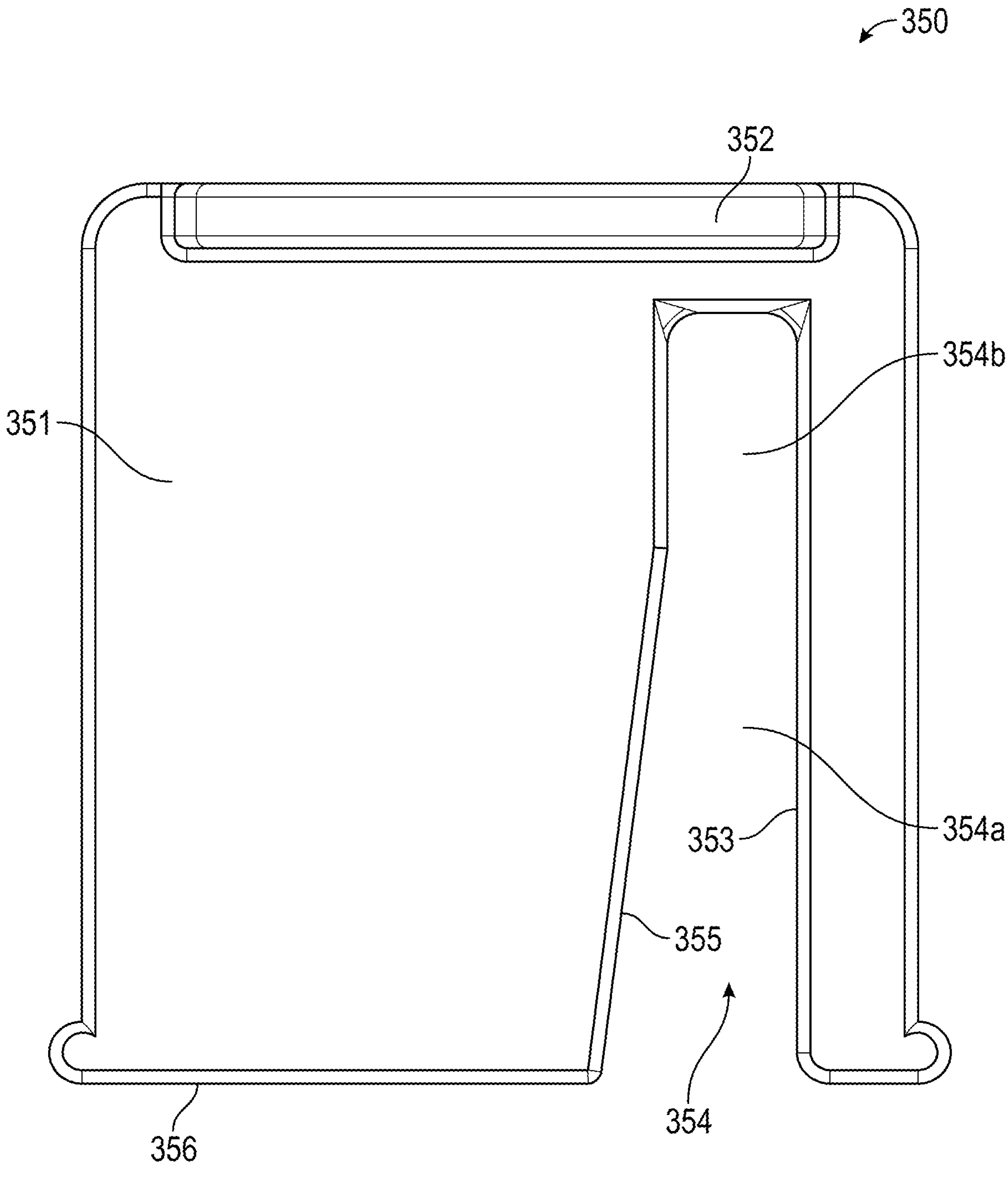


FIG. 11

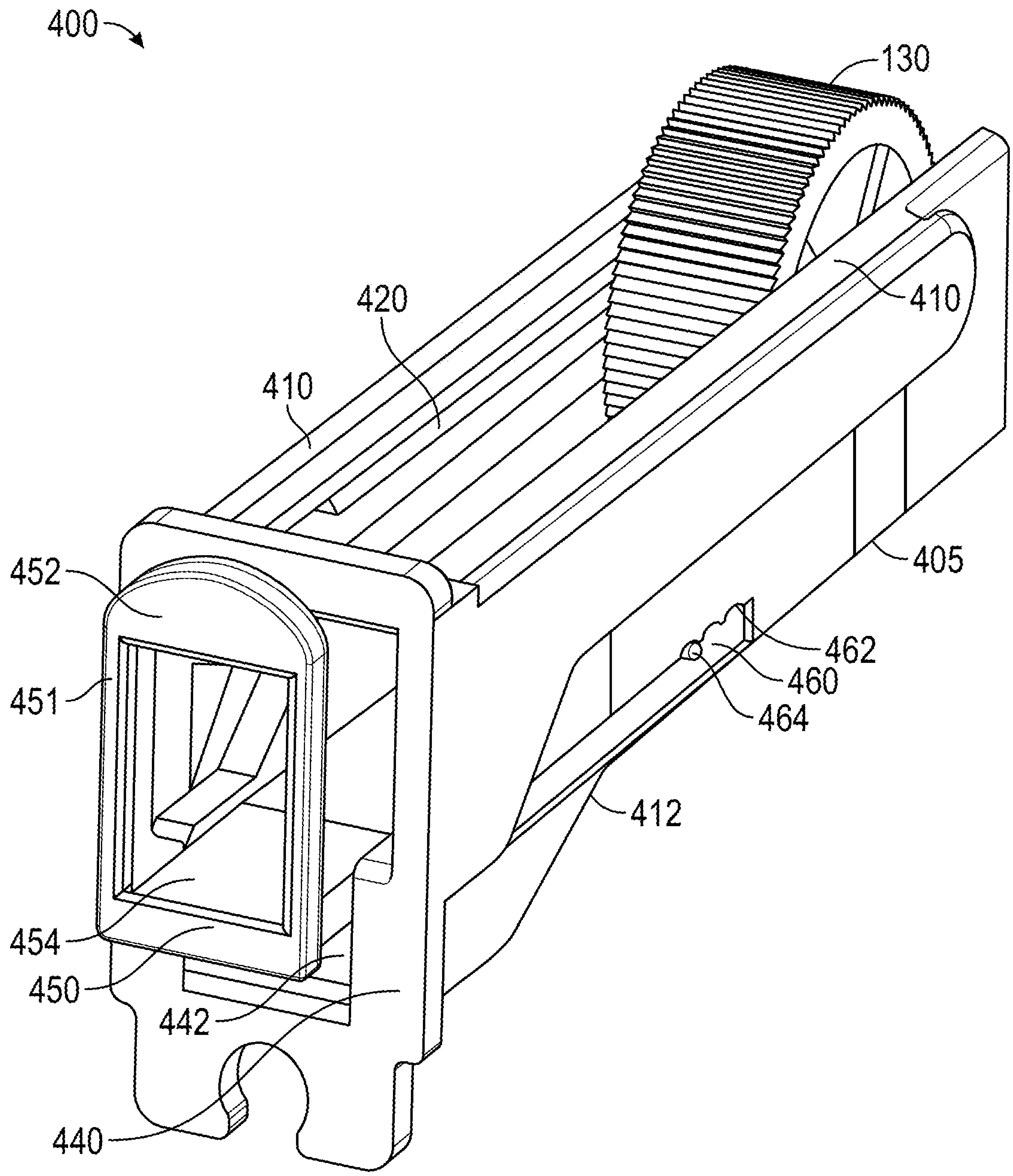


FIG. 12

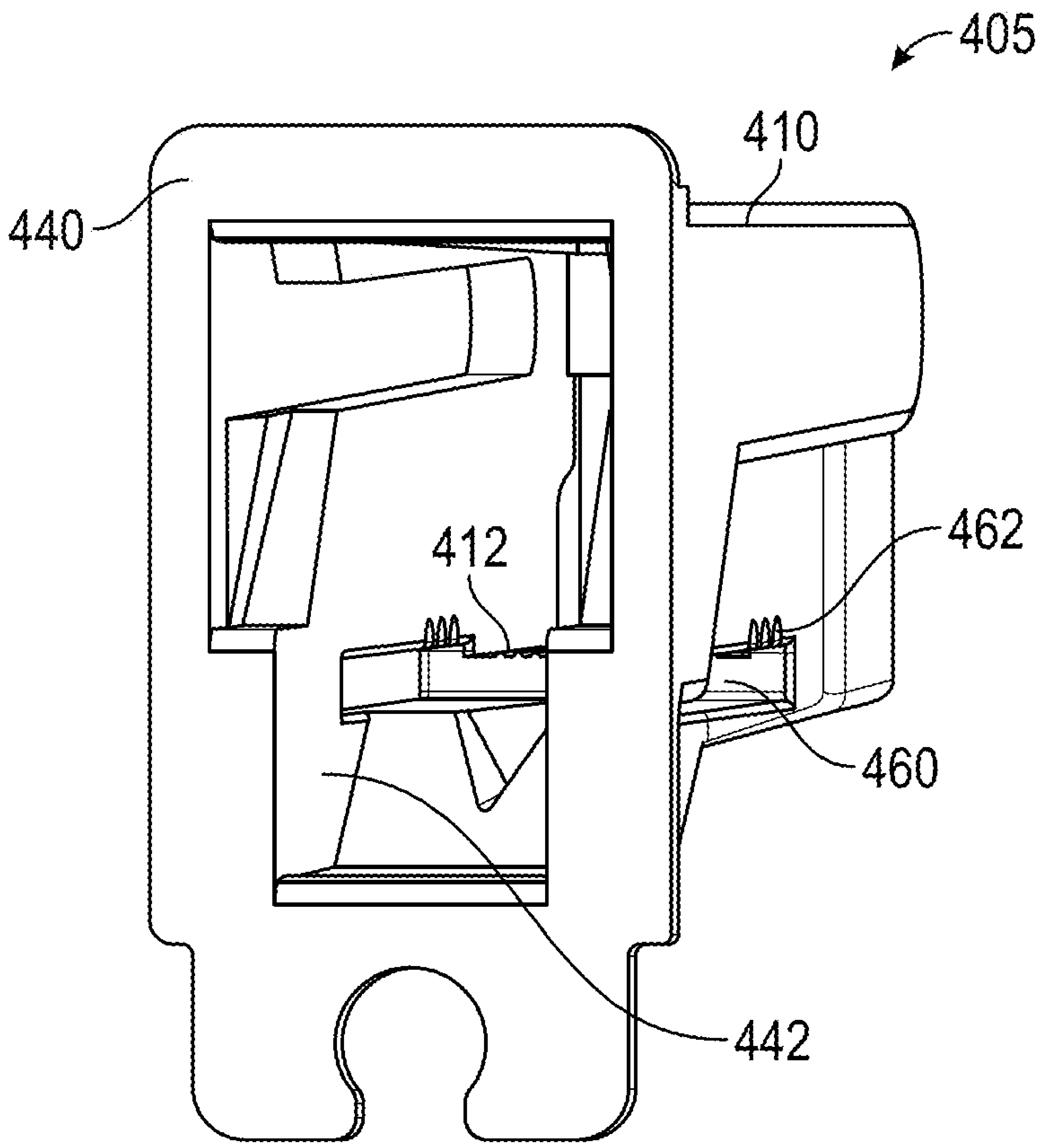


FIG. 13

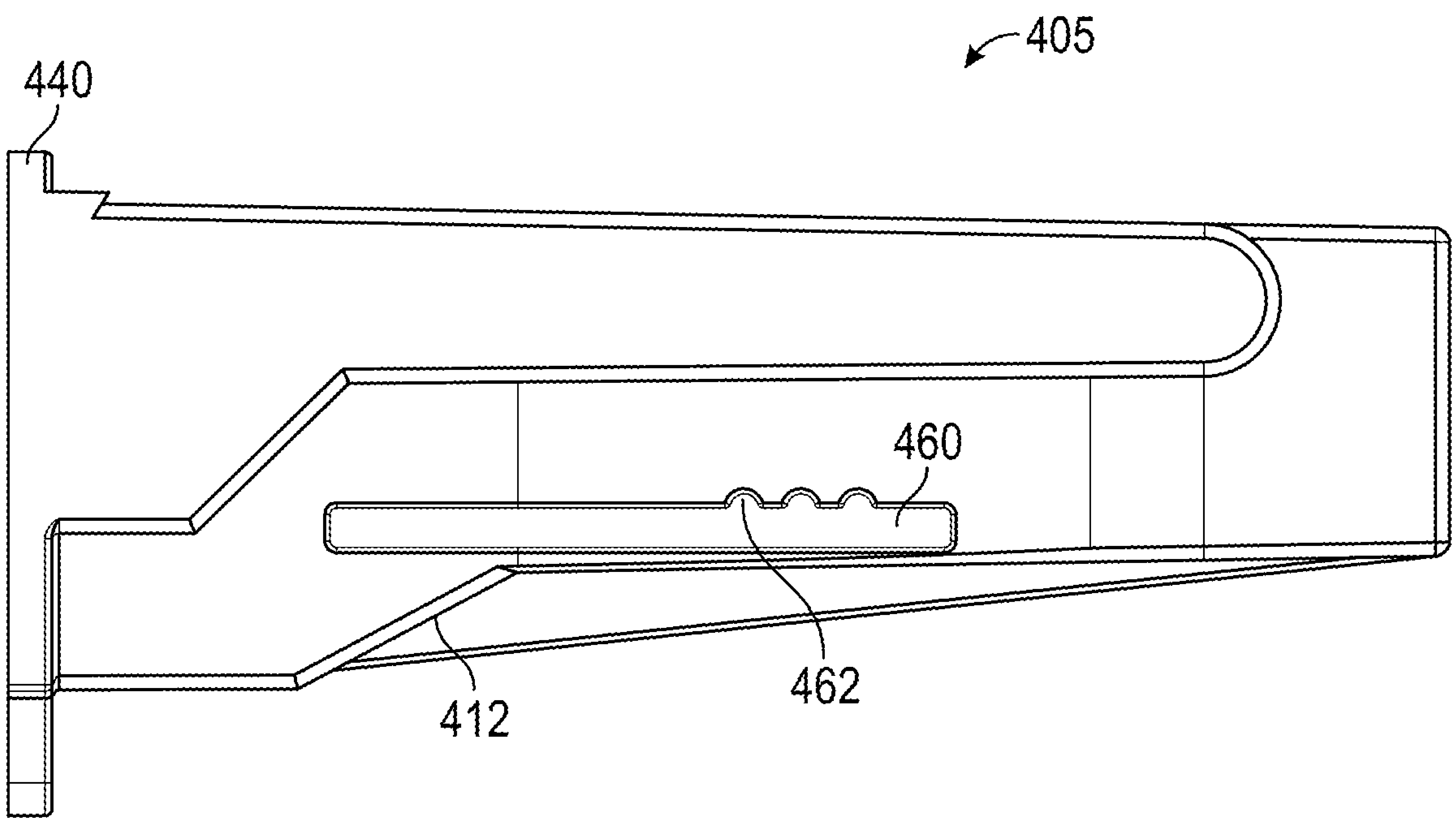


FIG. 14

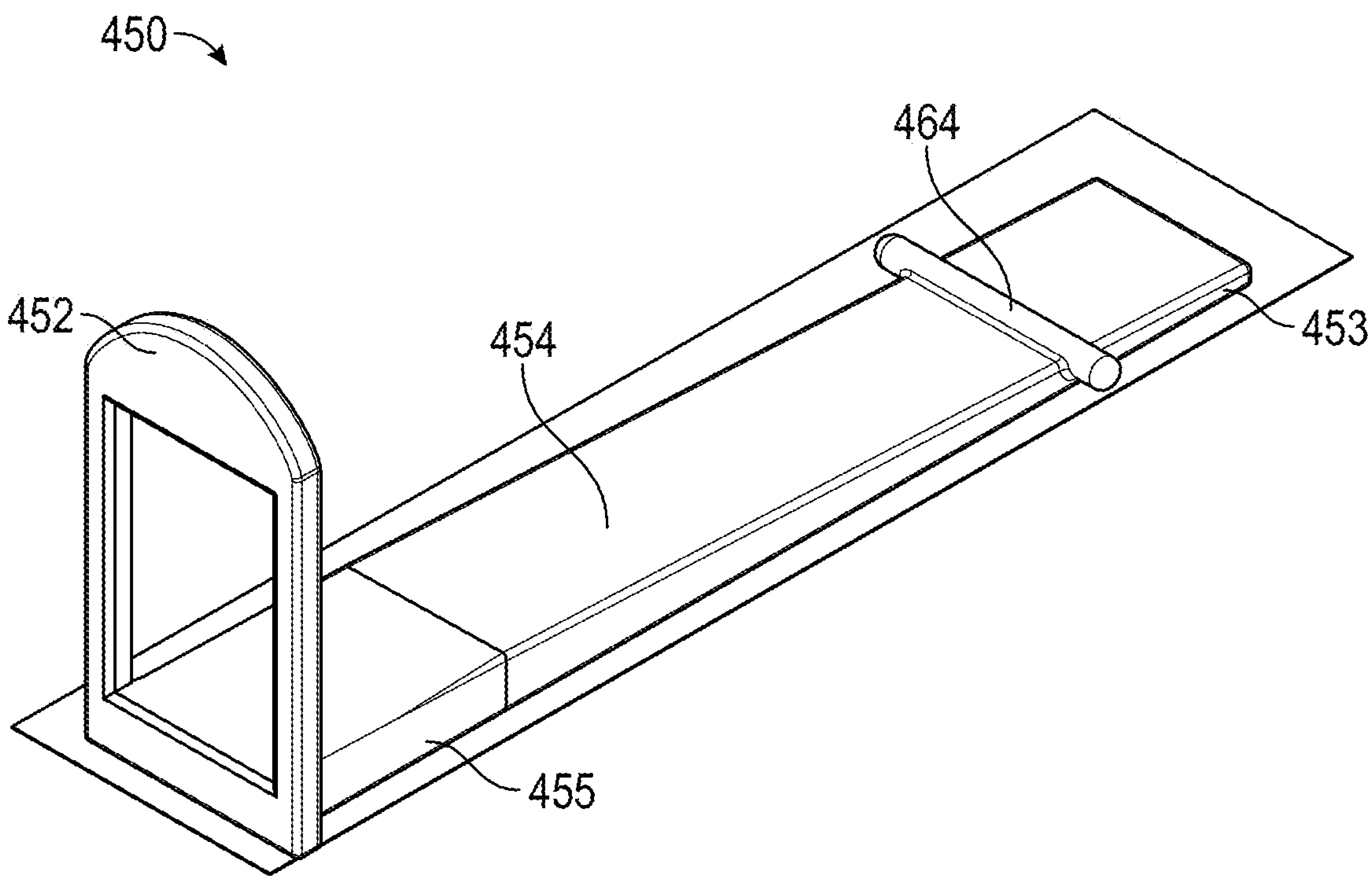

450
452
454
464
453
455

FIG. 15

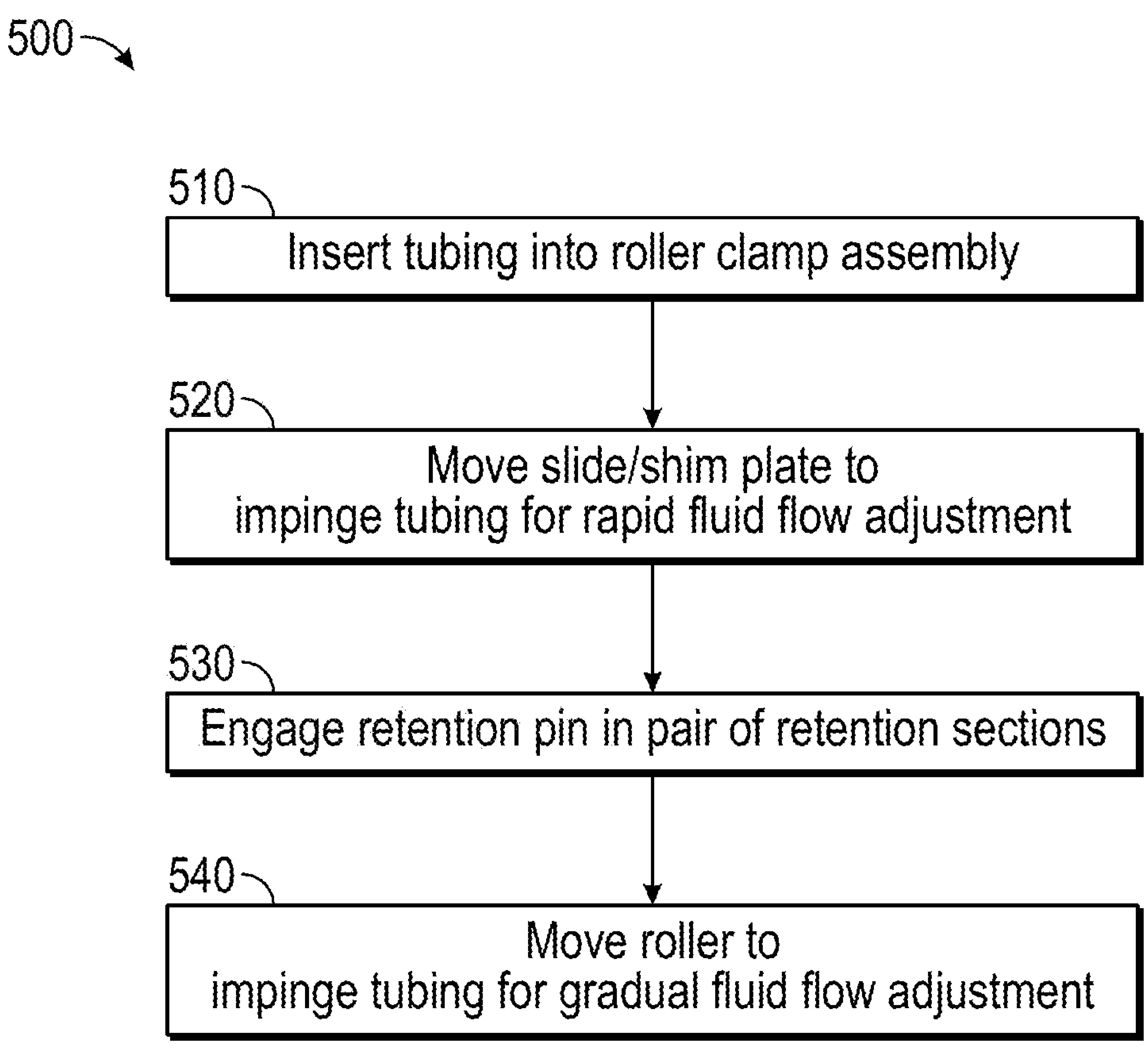

500
510
Insert tubing into roller clamp assembly
520
Move slide/shim plate to impinge tubing for rapid fluid flow adjustment
530
Engage retention pin in pair of retention sections
540
Move roller to impinge tubing for gradual fluid flow adjustment

FIG. 16

PRECISION ROLLER CLAMP

TECHNICAL FIELD

The present disclosure generally relates to a gravity intravenous (IV) set or infusion pump flow control device, and in particular a precision roller clamp assembly.

BACKGROUND

Flow controllers in the form of roller clamps are used in the medical field for intravenous (IV) applications. Typical roller clamps control a flow rate through an IV tube by clamping the tube in between a roller wheel and a housing. This approach, for one, provides a limited range of flow rate control because the roller wheel is essentially too sensitive in that a small movement of the roller wheel or dimension change causes a large change in flow rate of the fluid through the tube. Thus, the relatively course flow rate change provided by a typical roller clamp makes it difficult to provide precise flow control.

Also, typical roller clamps have flow rate drifting issues based on slippage of the roller wheel, such as when fluid pressure in the tube causes the roller wheel to roll back from the adjusted position. Further, typical roller clamps are sized for a specific IV set tube dimension, which requires having different sized roller clamps for use with various IV set tube dimensions.

Thus, it is desirable to provide a precision roller wheel assembly that works with multiple IV tube sizes, provides quick course flow rate adjustments and fine flow rate adjustments, and eliminates or minimizes roller wheel slippage.

SUMMARY

One or more embodiments provide a roller clamp assembly. The roller clamp assembly includes a housing configured to receive a portion of a connector tube of an infusion set. The housing includes two opposing side walls spaced apart from each other, each side wall having an opposing guide groove longitudinally positioned in an interior surface, a front wall disposed at one end of the side walls; and a guide wall disposed between the side walls, the guide wall converging along its length toward the position of the guide grooves. The roller clamp assembly also includes a roller wheel having two axial projections slidingly seated in the guide grooves, the roller configured to move along a longitudinal axis of the housing as the projections slide in the guide grooves, wherein spacing between the guide wall and the roller wheel decreases over a length of the guide wall. The roller clamp assembly further includes a plate configured to slideably engage with a portion of the housing. The plate includes a grip member and a tube engagement member configured to compress the connector tube a varying amount as the plate is moved in relation to the housing.

One or more embodiments provide a gravity infusion set. The infusion set includes a piercing spike, a drop chamber, a connector tube, a fitting and a roller clamp assembly. The roller clamp assembly includes a housing configured to receive a portion of a connector tube of an infusion set. The housing includes two opposing side walls spaced apart from each other, each side wall having an opposing guide groove longitudinally positioned in an interior surface, a front wall disposed at one end of the side walls; and a guide wall disposed between the side walls, the guide wall converging along its length toward the position of the guide grooves. The roller clamp assembly also includes a roller wheel having two axial projections slidingly seated in the guide grooves, the roller configured to move along a longitudinal axis of the housing as the projections slide in the guide grooves, wherein spacing between the guide wall and the roller wheel decreases over a length of the guide wall. The roller clamp assembly further includes a plate configured to slideably engage with a portion of the housing. The plate includes a grip member and a tube engagement member configured to compress the connector tube a varying amount as the plate is moved in relation to the housing.

One or more embodiments provide a method of adjusting a fluid flow rate through a connector tube coupled to a fluid source. The method includes inserting the connector tube through a housing of a roller clamp assembly having a roller wheel and a moveable plate; sliding the moveable plate relative to the housing to compress the connector tubing with a first impingement to produce a coarse adjustment that causes a rapid decrease in the fluid flow rate through the connector tube; and rolling the roller wheel relative to the housing to compress the connector tubing with a second impingement to produce a fine adjustment that causes a further gradual decrease in the fluid flow rate through the connector tube.

The foregoing and other features, aspects and advantages of the disclosed embodiments will become more apparent from the following detailed description and accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are included to provide further understanding of the disclosure and are incorporated in and constitute a part of this specification, illustrate embodiments of the disclosure and together with the description serve to explain the principles of the disclosure.

FIG. **1** depicts a perspective view of an example infusion set having a typical roller clamp.

FIG. **2** depicts a cross-section side view of the roller clamp of FIG. **1**.

FIG. **3** depicts a perspective view of a precision roller clamp assembly.

FIG. **4** depicts a top plan view of the precision roller clamp assembly of FIG. **3**.

FIG. **5** depicts a front elevation view of the precision roller clamp assembly of FIG. **3**.

FIG. **6** depicts a perspective view of a slide plate from the precision roller clamp assembly of FIG. **3**.

FIG. **7** depicts a cross-section perspective view of the precision roller clamp assembly of FIG. **3**.

FIG. **8** depicts a perspective view of a precision roller clamp assembly.

FIG. **9** depicts a perspective view of a slide plate from the precision roller clamp assembly of FIG. **8**.

FIG. **10** depicts a perspective view of a precision roller clamp assembly.

FIG. **11** depicts a perspective view of a slide plate from the precision roller clamp assembly of FIG. **10**.

FIG. **12** depicts a perspective view of a precision roller clamp assembly.

FIG. **13** depicts a perspective view of a housing of the precision roller clamp assembly of FIG. **12**.

FIG. **14** depicts a side view of the housing of FIG. **13**.

FIG. **15** depicts a perspective view of a shim plate of the precision roller clamp assembly of FIG. **12**.

FIG. **16** depicts a method of using a precision roller clamp assembly.

DETAILED DESCRIPTION

The detailed description set forth below describes various configurations of the subject technology and is not intended to represent the only configurations in which the subject technology may be practiced. The detailed description includes specific details for the purpose of providing a thorough understanding of the subject technology. Accordingly, dimensions are provided in regard to certain aspects as non-limiting examples. However, it will be apparent to those skilled in the art that the subject technology may be practiced without these specific details. In some instances, well-known structures and components are shown in block diagram form in order to avoid obscuring the concepts of the subject technology.

It is to be understood that the present disclosure includes examples of the subject technology and does not limit the scope of the appended claims. Various aspects of the subject technology will now be disclosed according to particular but non-limiting examples. Various embodiments described in the present disclosure may be carried out in different ways and variations, and in accordance with a desired application or implementation.

The present disclosure relates to a roller clamp and in particular to a roller clamp for use in gravity infusion. The roller clamp regulates the flow rate of a medical fluid (for example a solution of a drug to be administered to a patient, or blood) flowing through a tube. Typically, a standard infusion set is used to infuse the fluid. An example of a standard infusion set is shown in FIG. **1**.

The infusion set includes a piercing spike **20** which may either be a sharp spike for piercing rubber stoppers or rounded and blunt for insertion into a bag. The spike contains one channel for fluid and optionally a second channel for venting. A vent **21** is usually present in the vicinity of the piercing spike to allow air to flow into the drop chamber **22**. The vent **21** may be provided with a bacterial filter to prevent bacteria from entering the equipment.

The drop chamber **22** has a drop generator **23** at the top of the drop chamber **22** that produces drops of a certain size. Drops from the drop generator **23** fall into the drop chamber **22** such that the drop chamber **22** is partially filled with liquid. This prevents air bubbles from entering the connector tube **24**, which would be harmful to a patient. A particle filter may be provided at the lower aperture of the drop chamber **22**.

The connector tube **24** connects the drop chamber **22** with the patient. The connector tube **24** is usually around 150 cm long and can be manufactured from PVC. The tube **24** is shown shortened in FIG. **1** for clarity. The connector tube **24** typically has a continuous diameter throughout the length of the tube.

At the end of the connector tube **24** is a Luer fitting **25** which is standardized for connection to all other pieces of apparatus having a standard Luer cone. The person skilled in the art will appreciate that the Luer fitting **25** can be fitted to a hypodermic needle (not shown) for infusing the medical fluid into the circulatory system of a patient (e.g., into a vein).

Between the drop chamber **22** and the Luer fitting **25** and engaging with the connector tube **24**, is a roller clamp **26**. The present disclosure is concerned with an improved roller clamp assembly, but a typical roller clamp **26** as known in the art will now be described for background information.

The roller clamp **26** illustrated in FIG. **2** has two opposing side walls **27** having a pair of guide grooves **30** that are aligned with each other and face each other. A flow-regulating roller **28** is provided having axially-projecting shafts **29** protruding from the centers of each side of the roller **28**. The roller **28** is shown in outline for clarity. The shafts **29** of the roller **28** are captured by and seated in the guide grooves **30** so that the roller **28** can move up and down the guide grooves **30** as indicated by the arrows in FIG. **2**.

The entire roller clamp **26** has four walls (see FIG. **1**) in an open-ended boxlike construction and is dimensioned and configured to receive the connector tube **24**. In use, the tube **24** passes through the roller clamp **26**, between the two opposing side walls **27**, the roller **28** and a guide wall **31** that is opposed to the roller **28**.

In the roller clamp **26**, the surface of the guide wall **31** converges along its length toward the position of the guide grooves **30** in the downward direction of the guide grooves **30** (e.g., in the direction of the arrows in FIG. **2**). This tends to urge the connector tube **24** within the roller clamp **26** toward the guide grooves **30** and thus toward roller **28**.

Thus, rolling the roller **28** downwardly along the guide grooves **30** in the direction of the gradually closer guide wall **31** in the direction of the arrows causes the roller **28** to impinge against the connector tube **24**. As the roller **28** impinges on the tube **24**, the tube **24** becomes squeezed, as it is a flexible material such as PVC, and the lumen of the infusion tube **24** therefore becomes smaller. In this way, by narrowing of the lumen, the flow rate of liquid passing through the connector tube **24** can be regulated.

Thus, the roller clamp **26** controls the flow rate through the infusion tube **24** by clamping the infusion tube **24** between the roller **28** and the guide wall **31**. As discussed above, this provides for a course flow rate change because a small movement of the roller **28** causes a large change in the flow rate of the fluid through the tube **24**. Also, the force of the fluid in the tube **24** exerts a biasing force against the roller **28**, which often leads to slippage of the roller **28** (e.g., the roller **28** rolls back) from the adjusted position. In addition, the roller **28** needs to be sized for the tube **24** dimensions, so if a different size (e.g., diameter) tubing is used, a different size roller must then be used as well.

With reference to FIGS. **3**-**7**, a multistage precision roller clamp assembly **100** is shown. The roller clamp assembly **100** has a housing **105** having an open-ended boxlike construction and is dimensioned and configured to receive tubing, such as connector tube **24**. Two opposing side walls **110** each have a guide groove **120** that are aligned with each other and face each other. A flow-regulating roller **130** is provided having axially-projecting shafts **132** protruding from the centers of each side of the roller **130**. The shafts **132** of the roller **130** are seated in the guide grooves **120** so that the roller **130** can move up and down the guide grooves **120**. A guide wall **112** is opposed to the roller **130** and the surface of the guide wall **112** converges along its length toward the position of the guide grooves **120**.

In use, the tube **24** passes through the roller clamp assembly **100**, between the two opposing side walls **110**, the roller **130** and the guide wall **112** that is opposed to the roller **130**. Rolling the roller **130** downwardly along the guide grooves **120** in the direction of the gradually closer guide wall **112** causes the roller **130** to impinge against the tube **24**. As the roller **130** impinges on the tube **24**, the tube **24** becomes squeezed, as it is a flexible material such as PVC, and the lumen of the infusion tube **24** therefore becomes smaller. In this way, by narrowing of the lumen, the flow rate of liquid passing through the connector tube **24** can be regulated.

However, regulation of the fluid flow rate by adjusting the roller **130** may provide a large change in flow rate for a small movement of the roller **130**. For example, with the roller **130** in a wide open position where the roller **130** does not impinge on the tube **24**, a fluid flow rate may be anywhere from 2,000 to 8,000 milliliters per hour (ml/hr). This flow rate may be too fast to count drips in a drip chamber (e.g., drop chamber **22**) as the maximum flow rate for counting drops may be 250 ml/hr. Thus, for flow rates above 250 ml/hr, the roller **130** may have difficulty precisely controlling or adjusting the flow rate.

Accordingly, the precision roller clamp assembly **100** also includes a front wall **140** disposed at one end of the side walls **110**. The front wall **140** includes grooves **142** configured to receive a slide plate **150**. The slide plate **150** includes a plate wall **151**, a grip member **152** and a tube engagement channel **154**. The grip member **152** may protrude out (e.g., project orthogonally) from the plate wall **151** and provide a surface that may be pushed or pulled to slidably move the slide plate **150** within the grooves **142**, the slide plate **150** being movable towards or away from the tube **24** disposed through the roller clamp assembly **100**.

The tube engagement channel **154** may be configured to engage with the tube **24** and provide coarse control (e.g., rapid change) of the fluid flow rate through the tube **24**. For example, as shown in FIGS. **5** and **6**, the tube engagement channel **154** may have a first portion **154*a*** having a uniform width, a second portion **154*b*** having a linearly decreasing width, and a third portion **154*c*** having a uniform width narrower than the width of the first portion. The different widths of the first, second and third portions **154*a***, **154*b***, **154*c***, allows the tube engagement channel **154** to engage with tube **24** of various sizes (e.g., diameters), for example. As another example, the different widths of the first, second and third portions **154*a***, **154*b***, **154*c***, allows the tube engagement channel **154** to provide different levels of compression or impingement on the same sized tube **24** based on how fare the slide plate **150** is moved towards the tube **24**. The tube engagement channel **154** may be disposed centrally in a leading edge **156** of the slide plate **150**, and the tube engagement channel **154** may have a steeple shape, as shown in FIG. **5**.

For example, the slide plate **150** may be moved from a wide open position (e.g., not impinging upon tube **24**) to an engaged position in which the tube **24** is engaged within the tube engagement channel **154**. Thus, the slide plate **150** provides a coarse control where the fluid flow rate of 2,000 to 8,000 ml/hr in the wide open position may be quickly adjusted to a fluid flow rate of 250 ml/hr when the slide plate **150** is moved into the engaged position. As another example, the fluid flow rate may be quickly adjusted to a fully blocked flow rate of 0 ml/hr (e.g., quick occlusion), or any other desired fluid flow rate between 250 ml/hr and 0 ml/hr (e.g., 50 ml/hr, 125 ml/hr), when the slide plate **150** is moved into the fully engaged position. Thus, the slide plate **150** may be configured as a substantially binary flow switch (e.g., on/off switch), for example, where the flow rate is either wide open or adjusted down to a specific flow rate such as 250 ml/hr, or even to a fully blocked flow rate of 0 ml/hr.

The combination of the slide plate **150** and the roller **130** provides for both coarse and fine control of the fluid flow in tube **24**. For example, with both the slide plate **150** and the roller **130** in their respective wide open positions, the slide plate **150** may be moved to the engaged position, thus quickly adjusting the fluid flow rate of 2,000 to 8,000 ml/hr down to 250 ml/hr, or even to a fully blocked flow (e.g., quick occlusion). For an adjusted fluid flow rate that is not fully occluded, the roller **130** may then be moved within the housing **105** to increasingly impinge further upon tube **24** in a more gradual manner, providing a finer and more precise adjustment of the fluid flow rate. For example, the roller **130** may be moved from its wide open position near one end of the housing **105** in which the fluid flow rate is 250 ml/hr to a fully impinging position towards the opposite end of the housing **105** in which the fluid flow rate is 0 ml/hr (e.g., fully blocked). The length of travel of the roller **130** between the two positions allows for granular and precise changes in fluid flow rate via the roller **130** with the slide plate **150** engaged. For an adjusted fluid flow rate that is fully occluded after full engagement of the slide plate **150**, movement of the roller **130** may not be needed nor provide further flow rate adjustment.

The precision roller clamp assembly **100** may be configured so that the slide plate **150** is automatically moved to the fully engaged position when the roller **130** is moved from its wide open position to an initial control position (e.g., where the roller **130** initially begins to impinge the tube **24**). In this manner, a user (e.g., healthcare provider, patient) or an adjustment device only needs to touch and adjust the roller **130**.

With reference to FIGS. **8** and **9**, a multistage precision roller clamp assembly **200** is shown. Many of the features of roller clamp assembly **200** are the same as that of roller clamp assembly **100** and the same reference numbers are used for those features. The roller clamp assembly **200** has a housing **105** having an open-ended boxlike construction and is dimensioned and configured to receive tubing, such as connector tube **24**. Two opposing side walls **110** each have a guide groove **120** that are aligned with each other and face each other. A flow-regulating roller **130** is provided having axially-projecting shafts **132** protruding from the centers of each side of the roller **130**. The shafts **132** of the roller **130** are seated in the guide grooves **120** so that the roller **130** can move up and down the guide grooves **120**. A guide wall **112** is opposed to the roller **130** and the surface of the guide wall **112** converges along its length toward the position of the guide grooves **120**.

The roller clamp assembly **200** also includes a front wall **140** disposed at one end of the side walls **110**. The front wall **140** includes grooves **142** configured to receive a slide plate **250**. The slide plate **250** includes a plate wall **251**, a grip member **252** and a tube engagement channel **254**. The grip member **252** may protrude out (e.g., project orthogonally) from the plate wall **251** and provide a surface that may be pushed or pulled to slidably move the slide plate **250** within the grooves **142**, the slide plate **250** being movable towards or away from the tube **24** disposed through the roller clamp assembly **200**.

The tube engagement channel **254** may be configured to engage with the tube **24** and provide coarse control (e.g., rapid change) of the fluid flow rate through the tube **24**. For example, as shown in FIG. **9**, the tube engagement channel **254** may have a first portion **254*a*** having a linearly decreasing width and a second portion **254*b*** having a uniform width. The varying width of the first portion **254*a*** allows the tube engagement channel **254** to engage with tube **24** of various sizes (e.g., diameters), for example. As another example, the varying width of the first portion **254*a*** allows the tube engagement channel **254** to provide different levels of compression or impingement on the same sized tube **24** based on how far the slide plate **250** is moved towards the tube **24**. The tube engagement channel **254** may be disposed centrally in the slide plate **250** and linearly narrow inwards from a leading edge **256** of the slide plate **250**. Thus, the tube engagement channel **254** may have a substantially triangular shape, as shown in FIG. **9**.

For example, the slide plate **250** may be moved from a wide open position (e.g., not impinging upon tube **24**) to an initial engaged position in which the tube **24** is initially engaged but not impinged by the tube engagement channel **254**. From the initial engaged position, the slide plate **250** may be moved further towards the tube **24** such that the tube **24** is engaged by narrower portions of the tube engagement channel **254**, which impinges the tube **24** to a greater degree and causes a reduction in the fluid flow rate. The slide plate **250** may have a fully engaged position in which the tube **24** is engaged by narrow most portions of the tube engagement channel **254**. Thus, the slide plate **250** provides a coarse control where, for example, the fluid flow rate of 2,000 to 8,000 ml/hr in the wide open position may be quickly adjusted to a fluid flow rate of 250 ml/hr when the slide plate **250** is moved into the fully engaged position. As another example, the fluid flow rate may be quickly adjusted to a fully blocked flow rate of 0 ml/hr (e.g., quick occlusion), or any other desired fluid flow rate between 250 ml/hr and 0 ml/hr (e.g., 50 ml/hr, 125 ml/hr), when the slide plate **250** is moved into the fully engaged position. Positioning the slide plate **250** between the wide open position and the fully engaged position will result in the fluid flow rate being between the wide open rate and the fully engaged rate. Thus, the slide plate **250** may be configured as a linearly adjusting flow switch (e.g., dimmer switch), for example, where the flow rate linearly adjusts down from a wide open flow rate to a final coarse flow rate (e.g., 250 ml/hr), or even to a fully blocked flow rate (e.g., 0 ml/hr).

The combination of the slide plate **250** and the roller **130** provides for both coarse and fine control of the fluid flow in tube **24**. For example, with both the slide plate **250** and the roller **130** in their respective wide open positions, the slide plate **250** may be moved towards or to the fully engaged position, thus quickly adjusting the fluid flow rate anywhere from the wide open rate of 2,000 to 8,000 ml/hr down to 250 ml/hr, or even to a frilly blocked flow (e.g., quick occlusion). For an adjusted fluid flow rate that is not fully occluded, the roller **130** may then be moved within the housing **105** to increasingly impinge further upon tube **24** in a more gradual manner, providing a finer and more precise adjustment of the fluid flow rate. For example, the roller **130** may be moved from its wide open position near one end of the housing **105** in which the fluid flow rate is 250 ml/hr to a frilly impinging position towards the opposite end of the housing **105** in which the fluid flow rate is 0 ml/hr (e.g., fully blocked). The length of travel of the roller **130** between the two positions allows for granular and precise changes in fluid flow rate via the roller **130** with the slide plate **250** partially or frilly engaged. For an adjusted fluid flow rate that is fully occluded after full engagement of the slide plate **250**, movement of the roller **130** may not be needed nor provide further flow rate adjustment.

The precision roller clamp assembly **200** may be configured so that the slide plate **250** is automatically moved to a particular engaged position when the roller **130** is moved from its wide open position to an initial control position (e.g., where the roller **130** initially begins to impinge the tube **24**). In this manner, a user (e.g., healthcare provider, patient) or an adjustment device only needs to touch and adjust the roller **130**.

With reference to FIGS. **10** and **11**, a multistage precision roller clamp assembly **300** is shown. Many of the features of roller clamp assembly **300** are the same as that of roller clamp assembly **100** and the same reference numbers are used for those features. The roller clamp assembly **300** has a housing **105** having an open-ended boxlike construction and is dimensioned and configured to receive tubing, such as connector tube **24**. Two opposing side walls **110** each have a guide groove **120** that are aligned with each other and face each other. A flow-regulating roller **130** is provided having axially-projecting shafts **132** protruding from the centers of each side of the roller **130**. The shafts **132** of the roller **130** are seated in the guide grooves **120** so that the roller **130** can move up and down the guide grooves **120**. A guide wall **112** is opposed to the roller **130** and the surface of the guide wall **112** converges along its length toward the position of the guide grooves **120**.

The roller clamp assembly **300** also includes a front wall **140** disposed at one end of the side walls **110**. The front wall **140** includes grooves **142** configured to receive a slide plate **350**. The slide plate **350** includes a plate wall **351**, a grip member **352** and a tube engagement channel **354**. The grip member **352** may protrude out (e.g., project orthogonally) from the plate wall **351** and provide a surface that may be pushed or pulled to slidably move the slide plate **350** within the grooves **142**, the slide plate **350** being movable towards or away from the tube **24** disposed through the roller clamp assembly **300**.

The tube engagement channel **354** may be configured to engage with the tube **24** and provide coarse control (e.g., rapid change) of the fluid flow rate through the tube **24**. For example, as shown in FIG. **11**, the tube engagement channel **354** may have a first portion **354*a*** having a linearly decreasing width and a second portion **354*b*** having a uniform width. The varying width of the first portion **354*a*** allows the tube engagement channel **354** to engage with tube **24** of various sizes (e.g., diameters), for example. As another example, the varying width of the first portion **354*a*** allows the tube engagement channel **354** to provide different levels of compression or impingement on the same sized tube **24** based on how far the slide plate **350** is moved towards the tube **24**. The tube engagement channel **354** may be disposed offset to the center of the slide plate **350** (e.g., towards one side). The tube engagement channel **354** may have one straight side **353** and another angled side **355** having a portion that linearly narrows inwards from a leading edge **356** of the slide plate **350**. Thus, the tube engagement channel **354** may have a melded rectangular/angular shape, as shown in FIG. **11**.

For example, the slide plate **350** may be moved from a wide open position (e.g., not impinging upon tube **24**) to an initial engaged position in which the tube **24** is initially engaged but not impinged by the tube engagement channel **354**. From the initial engaged position, the slide plate **350** may be moved further towards the tube **24** such that the tube **24** is engaged by narrower portions of the tube engagement channel **354**, which impinges the tube **24** to a greater degree and causes a reduction in the fluid flow rate. The slide plate **350** may have a fully engaged position in which the tube **24** is engaged by narrow most portions of the tube engagement channel **354**. Thus, the slide plate **350** provides a coarse control where, for example, the fluid flow rate of 2,000 to 8,000 ml/hr in the wide open position may be quickly adjusted to a fluid flow rate of 250 ml/hr when the slide plate **350** is moved into the fully engaged position. As another example, the fluid flow rate may be quickly adjusted to a fully blocked flow rate of 0 ml/hr (e.g., quick occlusion), or any other desired fluid flow rate between 250 ml/hr and 0 ml/hr (e.g., 50 ml/hr, 125 ml/hr), when the slide plate **350** is moved into the fully engaged position. Positioning the slide plate **350** between the wide open position and the fully engaged position will result in the fluid flow rate being between the wide open rate and the fully engaged rate. Thus, the slide plate **350** may be configured as a linearly adjusting flow switch (e.g., dimmer switch), for example, where the flow rate linearly adjusts down from a wide open flow rate to a final coarse flow rate (e.g., 250 ml/hr), or even to a fully blocked flow rate (e.g., 0 ml/hr).

The combination of the slide plate **350** and the roller **130** provides for both coarse and fine control of the fluid flow in tube **24**. For example, with both the slide plate **350** and the roller **130** in their respective wide open positions, the slide plate **350** may be moved towards or to the fully engaged position, thus quickly adjusting the fluid flow rate anywhere from the wide open rate of 2,000 to 8,000 ml/hr down to 250 ml/hr, or even to a fully blocked flow (e.g., quick occlusion). For an adjusted fluid flow rate that is not fully occluded, the roller **130** may then be moved within the housing **105** to increasingly impinge further upon tube **24** in a more gradual manner, providing a finer and more precise adjustment of the fluid flow rate. For example, the roller **130** may be moved from its wide open position near one end of the housing **105** in which the fluid flow rate is 250 ml/hr to a fully impinging position towards the opposite end of the housing **105** in which the fluid flow rate is 0 ml/hr (e.g., fully blocked). The length of travel of the roller **130** between the two positions allows for granular and precise changes in fluid flow rate via the roller **130** with the slide plate **350** partially or fully engaged. For an adjusted fluid flow rate that is fully occluded after full engagement of the slide plate **350**, movement of the roller **130** may not be needed nor provide further flow rate adjustment.

The precision roller clamp assembly **300** may be configured so that the slide plate **350** is automatically moved to a particular engaged position when the roller **130** is moved from its wide open position to an initial control position (e.g., where the roller **130** initially begins to impinge the tube **24**). In this manner, a user (e.g., healthcare provider, patient) or an adjustment device only needs to touch and adjust the roller **130**.

With reference to FIGS. **12-15**, a multistage precision roller clamp assembly **400** is shown. Some of the features of roller clamp assembly **400** are the same as that of roller clamp assembly **100** and the same reference numbers are used for those features. The roller clamp assembly **400** has a housing **405** having an open-ended boxlike construction and is dimensioned and configured to receive tubing, such as connector tube **24**. Two opposing side walls **410** each have a guide groove **420** that are aligned with each other and face each other. A flow-regulating roller **130** is provided having axially-projecting shafts **132** protruding from the centers of each side of the roller **130**. The shafts **132** of the roller **130** are seated in the guide grooves **420** so that the roller **130** can move up and down the guide grooves **420**. A guide wall **412** is opposed to the roller **130** and the surface of the guide wall **412** converges along its length toward the position of the guide grooves **420**.

The roller clamp assembly **400** also includes a front wall **440** disposed at one end of the side walls **410**. The front wall **440** includes an opening **442** configured to receive a shim plate **450**. The shim plate **450** includes a plate wall **451**, a grip member **452** and a tube engagement wall **454**. The grip member **452** may extend out (e.g., project linearly) from the plate wall **451** and provide a surface that may be pushed or pulled to slidably move the shim plate **450** back and forth within the housing **405**. The shim plate **450** is movable in parallel with the tube **24** disposed through the roller clamp assembly **400**, so that the thickness of the tube engagement wall **454** may vary at a particular portion of the tube **24**. For example, the tube engagement wall **454** may have a varying thickness with a thinnest portion **453** at one end and a thickest portion **455** at the other end (e.g., a shim). The tube engagement wall **454** may be configured to engage with the tube **24** and provide coarse control (e.g., rapid change) of the fluid flow rate through the tube **24**.

For example, the shim plate **450** may be moved from a wide open position in which the thinnest portion **453** of the tube engagement wall **454** may be engaged with but not impinging upon tube **24**, to an engaged position in which the thickest portion **455** of the tube engagement wall **454** is engaged with and impinging the tube **24**. Thus, the shim plate **450** provides a coarse control where the fluid flow rate of 2,000 to 8,000 ml/hr in the wide open position may be quickly adjusted to a fluid flow rate of 250 ml/hr when the shim plate **450** is moved into the engaged position. As another example, the fluid flow rate may be quickly adjusted to a fully blocked flow rate of 0 ml/hr (e.g., quick occlusion), or any other desired fluid flow rate between 250 ml/hr and 0 ml/hr (e.g., 50 ml/hr, 125 ml/hr), when the shim plate **450** is moved into the fully engaged position. Thus, the shim plate **450** may be configured as a linearly adjusting flow switch (e.g., dimmer switch), for example, where the flow rate linearly adjusts down from a wide open flow rate to a final coarse flow rate (e.g., 250 ml/hr), or even to a fully blocked flow rate (e.g., 0 ml/hr).

The combination of the shim plate **450** and the roller **130** provides for both coarse and fine control of the fluid flow in tube **24**. For example, with both the shim plate **450** and the roller **130** in their respective wide open positions, the shim plate **450** may be moved towards or to the fully engaged position, thus quickly adjusting the fluid flow rate anywhere from the wide open rate of 2,000 to 8,000 ml/hr down to 250 ml/hr, or even to a fully blocked flow (e.g., quick occlusion). For an adjusted fluid flow rate that is not fully occluded, the roller **130** may then be moved within the housing **405** to increasingly impinge further upon tube **24** in a more gradual manner, providing a finer and more precise adjustment of the fluid flow rate. For example, the roller **130** may be moved from its wide open position near one end of the housing **405** in which the fluid flow rate is 250 mar to a fully impinging position towards the opposite end of the housing **405** in which the fluid flow rate is 0 ml/hr (e.g., fully blocked). The length of travel of the roller **130** between the two positions allows for granular and precise changes in fluid flow rate via the roller **130** with the shim plate **450** partially or fully engaged. For an adjusted fluid flow rate that is fully occluded after full engagement of the shim plate **450**, movement of the roller **130** may not be needed nor provide further flow rate adjustment.

The precision roller clamp assembly **400** may be configured so that the shim plate **450** is automatically moved to a particular engaged position when the roller **130** is moved from its wide open position to an initial control position (e.g., where the roller **130** initially begins to impinge the tube **24**). In this manner, a user (e.g., healthcare provider, patient) or an adjustment device only needs to touch and adjust the roller **130**.

The housing **405** may include a guide channel **460** disposed within each side wall **410**. The guide channel **460** may have one or more retention sections **462** configured to receive a retention pin **464** coupled to the tube engagement wall **454**. For example, when the retention pin **464** is disposed within an opposing pair of retention sections **462**, the shim plate **450** may be held in place within the housing **405**. A pushing or pulling force on the grip member **452** may overcome the retention force of the retention pin **464** engaged with the retention sections **462**, allowing the tube engagement wall **454** to move further into or out of the housing **405**. Also, the shim plate **450** may be configured, via the angle of the shim plate **450** and the retention sections **462**, to prevent slippage of the roller **130** in order to minimize or prevent flow rate drifting. Accordingly, the roller **130** may only slip forwards to further close the clamping gap, but may be prevented from slipping backwards, thus preventing further opening the clamping gap.

With reference to FIG. **16**, a method **500** of operating a precision roller clamp assembly is provided. In step **510**, tubing (e.g., IV tubing) is placed or disposed in a precision roller clamp assembly **100**, **200**, **300**, **400**. For example, tube **24** may be inserted into housing **105**, **205**, **305**, **405** with both a slide/shim plate **150**, **250**, **350**, **450** and a roller **130** in wide open positions (e.g., not contacting or impinging the tube **24**).

The slide/shim plate **150**, **250**, **350**, **450** is moved to engage and impinge the tube **24** in step **520**. For example, the slide plate **150**, **250**, **350** may be moved on a front wall **140** end of the housing **105**, **205**, **305** orthogonally to and towards the tube **24** to cause a compression force to squeeze the contacted portion of the tube **24**, thus causing the fluid flow rate in the tube **24** to rapidly change to a lower flow rate (e.g., from a wide open rate of 2,000 to 8,000 ml/hr down to 250 ml/hr, or even to a frilly blocked flow or quick occlusion). As another example, the shim plate **450** may be moved further into the housing **405** in parallel with the tube **24**, causing a compression force to squeeze the contacted portion of the tube **24** and causing the fluid flow rate in the tube **24** to rapidly change to a lower flow rate. With the use of the shim plate **450**, the shim plate **450** is moved so that a retention pin **464** is received by a pair of retention sections **462** disposed in side walls **410** of the housing **405**, in step **530**.

In step **540**, the roller **130** may be moved to engage and impinge the tube **24**. For example, the roller **130** may be moved from the front wall **140**, **440** end of the housing **105**, **205**, **305**, **405** towards the opposite end of the housing **105**, **205**, **305**, **405** so that a narrowing between a guide wall **112**, **412** and the roller **130** causes the roller to compress or squeeze the contacted portion of the tube **24**, thus causing the fluid flow rate in the tube **24** to slowly change to a lower or blocked flow rate (e.g., from 250 ml/hr to 0 ml/hr).

The slide/shim plate **150**, **250**, **350**, **450** and the roller **130** may be adjusted independently to each other or in combination with each other to achieve the desired fluid flow rate in the tube **24**. For example, one of the slide/shim plate **150**, **250**, **350**, **450** and the roller **130** may be adjusted to impinge upon the tube **24** while the other of the slide/shim plate **150**, **250**, **350**, **450** and the roller **130** remain in the wide open position. As another example, adjustment of the roller **130** may automatically adjust the slide/shim plate **150**, **250**, **350**, **450**. Thus, any combination of coarse and fine adjustments may be made to the fluid flow rate in the tube **24**.

It is understood that any specific order or hierarchy of blocks in the methods of processes disclosed is an illustration of example approaches. Based upon design or implementation preferences, it is understood that the specific order or hierarchy of blocks in the processes may be rearranged, or that all illustrated blocks be performed. In some implementations, any of the blocks may be performed simultaneously.

The present disclosure is provided to enable any person skilled in the art to practice the various aspects described herein. The disclosure provides various examples of the subject technology, and the subject technology is not limited to these examples. Various modifications to these aspects will be readily apparent to those skilled in the art, and the generic principles defined herein may be applied to other aspects.

A reference to an element in the singular is not intended to mean "one and only one" unless specifically so stated, but rather "one or more." Unless specifically stated otherwise, the term "some" refers to one or more. Pronouns in the masculine (e.g., his) include the feminine and neuter gender (e.g., her and its) and vice versa. Headings and subheadings, if any, are used for convenience only and do not limit the invention.

The word "exemplary" is used herein to mean "serving as an example or illustration." Any aspect or design described herein as "exemplary" is not necessarily to be construed as preferred or advantageous over other aspects or designs. In one aspect, various alternative configurations and operations described herein may be considered to be at least equivalent.

As used herein, the phrase "at least one of" preceding a series of items, with the term "or" to separate any of the items, modifies the list as a whole, rather than each item of the list. The phrase "at least one of" does not require selection of at least one item; rather, the phrase allows a meaning that includes at least one of any one of the items, and/or at least one of any combination of the items, and/or at least one of each of the items. By way of example, the phrase "at least one of A, B, or C" may refer to: only A, only B, or only C; or any combination of A, B, and C.

A phrase such as an "aspect" does not imply that such aspect is essential to the subject technology or that such aspect applies to all configurations of the subject technology. A disclosure relating to an aspect may apply to all configurations, or one or more configurations. An aspect may provide one or more examples. A phrase such as an aspect may refer to one or more aspects and vice versa. A phrase such as an "embodiment" does not imply that such embodiment is essential to the subject technology or that such embodiment applies to all configurations of the subject technology. A disclosure relating to an embodiment may apply to all embodiments, or one or more embodiments. An embodiment may provide one or more examples. A phrase such an embodiment may refer to one or more embodiments and vice versa. A phrase such as a "configuration" does not imply that such configuration is essential to the subject technology or that such configuration applies to all configurations of the subject technology. A disclosure relating to a configuration may apply to all configurations, or one or more configurations. A configuration may provide one or more examples. A phrase such a configuration may refer to one or more configurations and vice versa.

In one aspect, unless otherwise stated, all measurements, values, ratings, positions, magnitudes, sizes, and other specifications that are set forth in this specification, including in the claims that follow, are approximate, not exact. In one aspect, they are intended to have a reasonable range that is consistent with the functions to which they relate and with what is customary in the art to which they pertain.

It is understood that the specific order or hierarchy of steps, operations or processes disclosed is an illustration of exemplary approaches. Based upon design preferences, it is understood that the specific order or hierarchy of steps, operations or processes may be rearranged. Some of the steps, operations or processes may be performed simultaneously. Some or all of the steps, operations, or processes may be performed automatically, without the intervention of a user. The accompanying method claims, if any, present elements of the various steps, operations or processes in a sample order, and are not meant to be limited to the specific order or hierarchy presented.

All structural and functional equivalents to the elements of the various aspects described throughout this disclosure that are known or later come to be known to those of ordinary skill in the art are expressly incorporated herein by reference and are intended to be encompassed by the claims. Moreover, nothing disclosed herein is intended to be dedicated to the public regardless of whether such disclosure is explicitly recited in the claims. No claim element is to be construed under the provisions of 35 U.S.C. § 112 (f) unless the element is expressly recited using the phrase "means for" or, in the case of a method claim, the element is recited using the phrase "step for." Furthermore, to the extent that the term "include," "have," or the like is used, such term is intended to be inclusive in a manner similar to the term "comprise" as "comprise" is interpreted when employed as a transitional word in a claim.

The Title, Background, Summary, Brief Description of the Drawings and Abstract of the disclosure are hereby incorporated into the disclosure and are provided as illustrative examples of the disclosure, not as restrictive descriptions. It is submitted with the understanding that they will not be used to limit the scope or meaning of the claims. In addition, in the Detailed Description, it can be seen that the description provides illustrative examples and the various features are grouped together in various embodiments for the purpose of streamlining the disclosure. This method of disclosure is not to be interpreted as reflecting an intention that the claimed subject matter requires more features than are expressly recited in each claim. Rather, as the following claims reflect, inventive subject matter lies in less than all features of a single disclosed configuration or operation. The following claims are hereby incorporated into the Detailed Description, with each claim standing on its own as a separately claimed subject matter.

The claims are not intended to be limited to the aspects described herein, but are to be accorded the full scope consistent with the language claims and to encompass all legal equivalents. Notwithstanding, none of the claims are intended to embrace subject matter that fails to satisfy the requirement of 35 U.S.C. § 101, 102, or 103, nor should they be interpreted in such a way.

What is claimed is:

1. A roller clamp assembly comprising:

a housing configured to receive a portion of a connector tube of an infusion set, the housing comprising:

two opposing side walls spaced apart from each other, each side wall having an opposing guide groove longitudinally positioned in an interior surface;

a front wall disposed at one end of the side walls; and

a guide wall disposed between the side walls, the guide wall converging along its length toward the position of the guide grooves;

a roller wheel having two axial projections slidingly seated in the guide grooves, the roller configured to move along a longitudinal axis of the housing as the projections slide in the guide grooves, wherein spacing between the guide wall and the roller wheel decreases over a length of the guide wall; and

a plate configured to slideably engage with a portion of the housing, the plate comprising:

a grip member; and

a tube engagement member configured to compress the connector tube a varying amount as the plate is moved in relation to the housing.

2. The roller clamp assembly of claim **1**, wherein sliding of the roller wheel in a direction of lesser spacing between the guide wall and the roller wheel causes the roller wheel to impinge on the connector tube to a gradually increasing extent, wherein the increased impingement of the roller wheel on the connector tube is configured to reduce a fluid flow rate through the connector tube.

3. The roller clamp assembly of claim **1**, wherein the front wall comprises two grooves, wherein each is configured to slidingly receive a portion of the plate.

4. The roller clamp assembly of claim **1**, wherein the tube engagement member is a channel centrally disposed on a leading edge of the plate.

5. The roller clamp assembly of claim **4**, wherein the channel comprises a first portion having a first uniform width, a second portion having a varying width that decreases as a distance from the leading edge of the plate increases, and a third portion having a second uniform width that is less than the first uniform width.

6. The roller clamp assembly of claim **4**, wherein the channel comprises a first portion having a varying width that decreases as a distance from the leading edge of the plate increases and a second portion having a uniform width.

7. The roller clamp assembly of claim **4**, wherein at least a portion of the channel comprises a linearly decreasing width as a distance from the leading edge of the plate increases.

8. The roller clamp assembly of claim **1**, wherein the tube engagement member is a channel disposed in an offset from central position on a leading edge of the plate.

9. The roller clamp assembly of claim **8**, wherein the channel comprises a first portion having a varying width that decreases as a distance from the leading edge of the plate increases and a second portion having a uniform width.

10. The roller clamp assembly of claim **8**, wherein the channel comprises a first straight side extending from the leading edge of the plate and a second opposing side having an angled portion extending from the leading edge of the plate.

11. The roller clamp assembly of claim **1**, wherein the housing has an open-ended boxlike construction.

12. The roller clamp assembly of claim **1**, wherein the plate is configured to provide a first amount of compression to the connector tube and the roller wheel is configured to provide a second amount of compression to the connector tube.

13. The roller clamp assembly of claim **12**, wherein the first amount of compression comprises a rapid impingement to the connector tube and the second amount of compression comprises a gradual impingement to the connector tube.

14. The roller clamp assembly of claim **1**, wherein each side wall comprises an opposing guide channel disposed on a longitudinal axis of the housing, each guide channel having one or more retention sections.

15. The roller clamp assembly of claim **14**, wherein the tube engagement member is a wall comprising a varying thickness.

16. The roller clamp assembly of claim **15**, further comprising a retention pin coupled to the wall, the retention pin configured to be received by a pair of opposing retention sections.

17. The roller clamp assembly of claim 15, wherein the wall is configured to be slidably moveable along the guide wall to provide a shim force on the connector tube.

18. A gravity infusion set comprising:
- a piercing spike;
- a drop chamber;
- a connector tube;
- a fitting; and
- a roller clamp assembly, the roller clamp assembly comprising:
  - a housing configured to receive a portion of a connector tube of an infusion set, the housing comprising:
  - two opposing side walls spaced apart from each other, each side wall having an opposing guide groove longitudinally positioned in an interior surface;
  - a front wall disposed at one end of the side walls; and
  - a guide wall disposed between the side walls, the guide wall converging along its length toward the position of the guide grooves;
  - a roller wheel having two axial projections slidingly seated in the guide grooves, the roller configured to move along a longitudinal axis of the housing as the projections slide in the guide grooves, wherein spacing between the guide wall and the roller wheel decreases over a length of the guide wall; and
  - a plate configured to slideably engage with a portion of the housing, the plate comprising:
    - a grip member; and
    - a tube engagement member configured to compress the connector tube a varying amount as the plate is moved in relation to the housing.

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